PATENT
Attorney Docket No. 249.303

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors	:	Joseph S. Bieganek and Thomas R. Hetzel
Serial No.	:	10/628,860
Filed	:	July 28, 2003
Title	:	CONTOURED SEAT CUSHION AND METHOD FOR OFFLOADING PRESSURE FROM SKELETAL BONE PROMINENCES AND ENCOURAGING PROPER POSTURAL ALIGNMENT
Group Art Unit	:	3673
Confirmation No.	:	3850
Examiner	:	Michael Safavi

Declaration of Thomas R. Hetzel

I, Thomas R. Hetzel, declare as follows:

1. I am a coinventor of the inventions described in the above identified application. I am also the Chief Executive Officer of, and a principal shareholder in, Aspen Seating, Inc. and Ride Designs, to whom the above identified application has been assigned and/or licensed.

2. My resume is attached as Exhibit A to this Declaration. I am a licensed professional Physical Therapist (PT) and a Assistive Technology Practitioner (ATP). An ATP is a board exam certification administered by the Rehabilitation Engineering and Assistive Technology Association of North America (RESNA).

3. I have been involved in the fields of wheelchair seating and positioning products for use in clinical physical therapy applications for at least the last 16 years. In this regard, I have been involved in clinical practice, education, and the research and development of clinical wheelchair seating products. Through this experience, I have become reasonably familiar with those commercially-available seating products which are widely used in or prescribed for clinical and medical applications to attempt to

resolve comfort, posture, and skin sore or ulcer problems prevalent in individuals confined to wheelchairs.

4. In my present position as CEO of Aspen Seating and Ride Designs, I oversee and educate Physical Therapists and other clinicians who are directly involved in the treatment and physical therapy of wheelchair users through the use of the Aspen Seating and Ride Designs products, including the product described in the above identified patent application. I have also been a presenter at many national and international conferences and symposiums having to do with physical therapy as it relates to seating and related problems encountered wheelchair users. I am the author of the articles attached as Exhibits B, C and D, all of which have been published in peer-reviewed publications. The article of the Exhibit B specifically relates to and provides background considerations relevant to my co-invention described above.

5. The article attached in Exhibit E describes the benefits of my co-invention, but this article was authored by an independent clinician having a Masters degree in Physical Therapy. The article of Exhibit E was presented at the 22nd International Seating Symposium in March of this year. The article of Exhibit E demonstrates the utility and importance of my co-invention in situations where other type of seating devices could not achieve adequate results.

6. Aspen Seating and Ride Designs manufacture and distribute seating cushions embodying my co-invention. Those seating cushions have been granted approval for prescription under the US Medicare program. In order to qualify the cushions for prescription under the US Medicare program, it was necessary to have the cushions tested to prove their protective value against skin sores and ulcers for high risk patients.

7. In order to obtain this Medicare approval, there were two recognized test programs which could be followed. One test program involves the mechanical measurement of deflection force of the cushion at high risk pelvic areas at the bony prominences. This test program could not be used with the cushion embodying my co-invention because my co-invention provides relief areas which substantially offload pressure from the bony prominences. Consequently, a mechanical force deflection

measurement at the high risk bony prominence areas was meaningless because my co-invention offers no support from those areas. As a result, Aspen Seating and Ride Designs had to undertake human subject testing in order to obtain test data to qualify its cushions for prescription under the Medicare program.

8. The human subject testing was performed on the Aspen Seating/Ride Designs cushion that embodies my co-invention by the Institute of Orthopaedics and Musculoskeletal Science, Aspire Centre for Disability Sciences, University College London, London, England during 2005. The results of the test were submitted to a Medicare- contracted organization which evaluates medical products for assignment of appropriate Medicare billing codes. Based on the human subject test results, the Aspen Seating/Ride Designs products embodying my co-invention were granted Medicare billing codes. This approval is indicated on the January 30, 2006 letter attached as Exhibit F.

9. Insofar as I have been able to determine, Aspen Seating/Ride Designs is the only company which has been granted a Medicare billing code for prescription of its therapeutic seating products based on human subject testing. It is my information and belief that all other therapeutic seating products which have been granted a Medicare billing code have been tested using the mechanical intention. This information infers that no other Medicare-approved therapeutic seating products are therefore constructed and operative to substantially offload pressure from the bony prominences, although I have no direct information to confirm this point.

10. I am not aware of any commercially-available therapeutic seating products which have the construction and function of the Aspen Seating/Ride Designs products which offload support pressure from the bony prominences at the ischial tuberosities, the coccyx and sacrum and the greater trochanters while simultaneously transferring the support pressure to the posterior lateral buttocks and beneath the proximal thigh bones.

11. I am a co-inventor of the inventions described in US patent applications for serial number 10/628,858 entitled Individually-Contoured Seat Cushion and Shape Capturing and Fabricating Method for Seat Cushion; serial number 10/766,623 entitled

Reinforced and Adjustable Contoured Seat Cushion and Method of Reinforcing and Adjusting the Contoured Seat Cushion; serial number 11/140,003 entitled Seat Cushion with Adjustable Contour and Method of Adjusting the Contour of a Seat Cushion; and serial number 11/546,771 entitled Reinforced and Adjustable Contoured Seat Cushion and Method of Reinforcing and Adjusting the Contoured Seat Cushion. I am also a coinventor of the inventions described in US patent 6,990,744 entitled Apparatus and Method for Evaluating Clearance from a Contoured Seat Cushion.

12. I have been asked to read and study US patent 5,845,352 to Matsler, US patent 5,617,595 to Landi, US patent 3,503,649 to Johnson, and US patent 4,912,788 to Lonardo, for the purpose of identifying any distinguishing features of my co-invention relative to the descriptions in those US patents. I have done so, and I believe my co-invention described in the above application to be different from the descriptions in those US patents for the reasons which I specifically discussed below with respect to each of these four US patents.

13. My comments specifically concerning US patent 5,845,352 to Matsler are stated in the following paragraphs 14 to 18.

14. A cushion similar to or the same as that described in the Matsler patent has been on the market for some time by Roho. I am generally familiar with this cushion. My understanding of the Roho cushion as marketed is generally consistent with the description of the cushion as described in the Matsler patent.

15. The cushion described in the Matsler patent does not have the same structure or function as my co-invention, because the cushion of the Matsler patent depends on even pressure distribution, which is unlike my co-invention which offload support pressure from the bony prominences and applies the support pressure to the broad tissue masses at the posterior lateral buttocks and beneath the proximal thigh bones. The cushion described in the Matsler patent is intended to achieve comfort, rather than support to eliminate risks of skin ulcers or to invoke proper posture as does my co-invention. In my opinion, the cushion described in the Matsler patent is inappropriate for patients having a high risk of skin ulcers.

16. The Matsler patent specifically describes that the cushion relies on pressure distribution, rather than offloading pressure. Column 3, lines 64-67 state that the side and rear walls of the cushion are too soft and thin to prevent the user from bottoming out without some assistance, and that the assistance to prevent bottoming out is provided by an air module which is positioned directly below the ischial tuberosities. Pressure is introduced into the air module, and that pressure is applied to the ischial tuberosities as support pressure. Also see column 2, lines 36 and 37 for a recognition that the air cells are required for support and force equalization beneath the ischial tuberosities. Consequently, the Matsler patent describes a cushion which introduces, and is dependent on, support pressure on the ischial tuberosities, rather than offloading the support pressure from the ischial tuberosities as required in my co-invention.

17. In addition, because of the support pressure introduced by the air module on the ischial tuberosities, the surface adjacent to the ischial tuberosities cannot be spaced relatively farther away from the pelvic anatomy than the support areas as is the case in my co-invention, because as described in Matsler patent, the support area on the ischial tuberosities contacts that bony prominence.

18. The Matsler patent also fails to describe rear support areas which are capable of introducing upward and forward support pressure on the lateral posterior buttocks, as is the case in my co-invention. As noted above, the side and rear walls of the cushion are too soft and thin to prevent the user from bottoming out. Bottoming out is prevented by the air module. The air module is beneath the ischial tuberosities, and therefore the area surrounding the air module at the back of the air module is too soft and thin to introduce any upward and forward support pressure on the posterior lateral buttocks, in my opinion. I note that the Matsler patent specifically mentions that the rear edges are lower than the front edges (column 3, lines 34-35), which again supports my opinion that the area at the back of the module will not introduce any upward and forward support pressure on the posterior lateral buttocks.

19. My comments specifically concerning <u>US patent 5,617,595 to Landi</u> are stated in the following paragraphs 20 to 25.

20. A cushion similar to or the same as that described in the Landi patent was marketed for some time by Supracor, who is noted on the cover page of the Landi patent as its assignee. I am generally familiar with the cushion marketed by Supracor. My understanding of the marketed Supracor cushion is generally consistent with the description of the cushion as described in the Landi patent.

21. The Landi patent describes a specific type of material, a thermoplastic elastomeric honeycomb, which achieves certain crush characteristics of deflection relative to compressive force, as shown in Figs. 7 and 8. The characteristics of this specific type of material adjust the amount of support to the prominences of the body of a seated user (See abstract).

22. The Landi patent does not describe offloading support pressure from certain areas of the body. Instead, all areas of the body are supported as a result of the cushion conforming to the body due to the crush characteristics of the special materials. Certain body contact areas have a lesser support pressure compared to the support pressures at other areas, due to the crush characteristics. It is in this sense that the Landi patent occasionally refers to relieving pressure. The reference to relieving pressure does not mean that the pressure is offloaded. Instead, what is meant is that the support pressure is distributed over all the areas with some areas receiving more support pressure than others. This is explained at column 8, line 42 to column 9, line 16, and specifically at column 8, lines 50-54 and column 9, lines 8-13.

23. The Landi patent specifically describes supporting the ischial tuberosities. See column 13, lines 59-63. This is different from my co-invention which offloads support pressure from the ischial tuberosities.

24. The Landi patent specifically describes supporting the greater trochanters. See column 14, lines 27-30, taken in reference to column 13, lines 34-38. This is different from my co-invention which offloads support pressure from the greater trochanters.

25. The Landi patent specifically describes supporting the entire upper leg over the length of the thigh bone. See column 14, lines 30-34. This is different from my co-invention which concentrates support pressure on only the proximal thigh bones.

Concentrating the support pressure on only the proximal thigh bones as is done in my co-invention allows the weight of the distal legs to act in a fulcrum-like manner through the support area beneath the proximal thighs to support the pelvic area.

26. My comments specifically concerning US patent 3,503,649 to Johnson are stated in the following paragraphs 27 to 35.

27. I am not aware that a cushion having a characteristics described in the Johnson patent has ever been marketed or used commercially.

28. The cushion described in the Johnson patent utilizes structure and functionality which is opposite in virtually every respect from the structure and functionality in my co-invention. Specifically, the Johnson patent describes loading the bony prominences of the pelvic area anatomy with support pressure, while my co-invention involves offloading support pressure from the bony prominences.

29. In my opinion, a cushion having the characteristics described in the Johnson patent would be dangerous for therapeutic seating, because of its proclivity to create pressure ulcers as a result of applying the support pressure to the bony prominences.

30. A cushion having a characteristics described in Johnson may be useful in forcing erect posture in a person who can respond normally, but forcing that erect posture would result in discomfort to the user. In my opinion, the erect posture could only be sustained for a relatively short time until the pain and discomfort created by the cushion caused the user to remove himself or herself from the cushion.

31. The Johnson patent specifically describes casting the weight of the upper body on the sacrum. See column 1, line 43. At column 3, lines 44-57, the concept of supporting the posterior superior iliac spines of the Ilium is described. The posterior superior iliac spines are bony prominences which are at the posterior termination of the iliac crests, adjacent and prominent to the lateral margins of the sacrum. The purpose of supporting the sacrum and posterior superior iliac spines, as described in the Johnson patent, is to position the coccyx where it will be relatively free of compressive loading. The engagement with the posterior superior iliac spines of the Ilium of the sacrum is specifically claimed in paragraph (b) of claim 1. Engaging the posterior

superior iliac spines is accomplished by the inverted V at 26 and 27 in the Johnson patent, which has its narrow point at the top where the sacrum has its widest part. Thus, Johnson describes loading the sacrum and posterior superior iliac spines for the purpose of offloading the coccyx. This is contrary to my co-invention which offloads support pressure from both the sacrum and the coccyx through elevated posterior and lateral support of gluteal muscle mass of the buttocks.

32. The Johnson patent also describes applying support pressure to the greater trochanters. This is described at column 3, lines 58-65. Although this description is in regard to the inclined surfaces 62 and 63 of the lateral support members 60 and 61 engaging the gluteus maximus of the upper leg, the surfaces 62 and 63 are anterior to the gluteal mass and clearly engage the greater trochanters. Engagement of the greater trochanters is illustrated in Fig. 3, where the greater trochanters are positioned directly above the support areas 62 and 63 (shown in Fig.1; not numbered in Fig. 3). The engagement with the greater trochanters is also confirmed in Fig. 5, which shows the support surface 63 slightly positioned in front of the coccyx C. The greater trochanters are located slightly in front of the coccyx in a typical human anatomy.

33. The Johnson patent describes applying support force to the ischial tuberosities. This is described in paragraph (c) of claim 1. This is contrary to my co-invention which offloads support pressure on the ischial tuberosities.

34. The Johnson patent also describes applying support forced to the front portion of the ischial tuberosities. The front portions of the ischial tuberosities are known as the inferior ramus of the ishium. As described in the Johnson patent, the inclined surfaces 55 on the sides or flanks of the dome 50 are intended to contact the front portion of the ischial tuberosities. This is clearly stated in paragraph (e) of claim 1. Again, my co-invention offloads support pressure from the ischial tuberosities, including the front portion or inferior ramus.

35. The Johnson patent describes a three point support for the pelvic girdle. See column 4, lines 2-4. The three point support applies support force to the bony prominences at the superior iliac spines of the Ilium of the sacrum, at the ischial

tuberosities, and at the inferior ramus of the ishium. The support of the bony prominences is all for the sake of relieving pressure on the tailbone or the coccyx. My co-invention offloads the support pressure from all of the areas where the Johnson patent applies support pressure.

36. My comments specifically concerning US patent 4,912,788 to Lonardo are stated in the following paragraphs 37 to 43.

37. I am not aware that a cushion having a characteristics described in the Lonardo patent has ever been marketed or used commercially.

38. The Lonardo patent describes pressure relief for the lesser trochanters, not the greater trochanters. The lesser trochanters are located in a different position on the thigh bone than the greater trochanters. The lesser trochanters are located forward and on the proximal medial aspect of the femur relative to the greater trochanters. The lesser trochanters are not even regarded in the literature as at risk for skin breakdown, and therefore pressure relief for the lesser trochanters is of questionable value, in my opinion.

39. The relief area for the lesser trochanters described in the Lonardo patent is approximately at the location of the support area underneath the proximal thigh bones in my co-invention. The commission described in the Lonardo patent is therefore incapable of providing a support area which acts as fulcrum at the proximal thigh bones by which to transfer weight from the distal legs through the hip joints to suspend pelvic area anatomy. Because the Lonardo patent describes a relief area where my co-invention presents a support area, Lonardo's cushion does not describe the support areas underneath the proximal thighs or use those support areas to transfer weight of the distal legs through the thigh bones to the hip joints to the pelvic area for suspending the bony prominences above the relief areas.

40. The Lonardo patent does not describe upward and forward support at the lateral posterior buttocks, which is part of my co-invention. Consequently, there is no description of the lateral posterior supports which induce upward and forward support pressure. The cushion described in the Lonardo patent appears to rely on the flexible lumbar back pad to provide forward support pressure on the lumbar area. The multi-

part flexible cushion described in the Lonardo patent appears to rely on the back panel of the wheelchair to maintain the position of the back panel. Any posture induced by the cushion described in the Lonardo patent results from the structure provided by the wheelchair, rather than by the cushion itself.

41. Because the Lonardo patent fails to describe or inherently provide the support areas at the posterior thigh bones and fails to describe or inherently provide upward and forward support at the posterior lateral buttocks, the cushion described in the Lonardo patent can not achieve the posture-inducing support for the pelvic area at the posterior lateral buttocks and from upward force transferred by the thigh bones to the hip joints as a result of the fulcrum-like action at the support area beneath the proximal thigh bones, as is part of my co-invention.

42. The Lonardo patent fails to describe an adequate relief area which surrounds the sacrum, in order to offload support pressure from the sacrum. Lonardo describes an inverted V which has its narrow point at the top where the sacrum has its widest part. This inverted V configuration is likely to contact the sacrum, in the same manner as has been described above in paragraph 30 with respect to the Johnson patent.

43. The Lonardo patent describes relief areas which, if effective at all, require precise positioning. The size of the relief areas will not provide an adequate amount of room to accommodate forward and backward movement of the ischial tuberosities, associated with normal dynamics of upper torso movement, without causing the ischial tuberosities to encounter pressure and shear forces at the margins of the relief area when rubbing against the cushion.

44. Based on the descriptions in the Matsler, Landi, Johnson and Lonardo patents, there is no undescribed functionality or structure of those references which would necessarily and invariably lead to my co-invention, or to the structure and functionality of my co-invention. This is so because there are described features in each one of the Matsler, Landi, Johnson and Lonardo patents which are directly contrary to at least one of the features of functionality or structure required in my co-invention. A feature which is directly contrary in function or structure can not

necessarily and invariably lead to the opposite feature in the context of seating cushions, in my opinion.

45. Based on the descriptions in the Matsler, Landi, Johnson and Lonardo patents, I am unable to imagine any other realistic, serious, therapeutic use of the cushions described in those patents, beyond the use in the manner specifically described in those patents. I am unable to imagine that any uses other than those specifically described in those patents would be medically or therapeutically appropriate and any such uses would likely be unsafe.

46. It has been my experience that any therapeutic cushion which is not used in accordance with its instructions and intended use creates problems for the user, and does not solve problems. Solutions to problems come from different cushions, not from uses outside of the scope of the intended and instructed use.

47. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the patent application or any patent issued thereon.

10-25-06

Date

Thomas R. Hetzel, PT, ATP

EXHIBIT A

RESUME

Thomas R. Hetzel, PT, ATP
Aspen Seating and Ride Designs
4251-E S. Natches Ct
Sheridan, CO 80110
303.781.1633

▶ PROFESSIONAL EXPERIENCE

Aspen Seating and Ride Designs
2000 - Present
Owner / CEO

Lead all elements of business, clinical services, and production for provision of highly custom wheelchair seating systems.

Humanity Over Technology, Nederland, CO **1996 - 2000**
Owner/President

Provide education, consultation, evaluation and treatment services, in the areas of wheelchair seating and mobility and therapeutic positioning, to consumers, providers, practitioners, the community, funding agencies, and manufacturers. Provided consultative services to the State of Tennessee supporting a federal mandate to improve services to institutionalized individuals with severe mental retardation and developmental disabilities. Provided consultative services for two legal cases, one including a deposition, concerning skin breakdown related to wheelchair seating equipment prescription and use. One case was dropped and the other settled out of court.

Jay Medical Ltd., Boulder, CO **1995 -1996**
Product and Education Manager

Managed the development and introduction of new seating and positioning products. Supervised the implementation of education programs.

Jay Medical Ltd., Boulder, CO **1992 -1995**
Education Specialist

Developed educational programs and materials to increase the base knowledge of consumers, providers, practitioners, the community, and funding agencies. Coordinated and presented international seminar series.

Easter Seals Rehabilitation Center, Columbus, OH **1991 - 1992**
Clinical Education Coordinator

Evaluation and treatment of individuals with special needs in early intervention, preschool, local school systems, and adult MR facilities. Coordinate student internships.

The Younker Rehabilitation Center, Des Moines, IA **1989 - 1991**
Staff Physical Therapist

Evaluation and treatment of adults with various neurological conditions.

▶ Education

Bachelor of Science - Physical Therapy, The Ohio State University, Cum Laude, 1989.

▶ Continuing Education

Prairie Seating and Mobility Conference, Winnipeg Attendee and presenter	2004, 2005
International Seating Symposium, Presenter	1993, 1994, 1995, 1996, 1997, 1998, 1999, 2001, 2004, 2005, 2006
Canadian Seating and Mobility Conference, Presenter	1993, 1994, 1995, 1996, 1997, 1998, 1999, 2004, 2005, 2006
National Home Health Care Expo attendee and/or presenter	1993, 1994, 1995, 1996, 1997, 1999, 2003, 2004, 2005, 2006
RESNA Annual Convention attendee and/or presenter	1993, 1994, 1995, 1996, 1998, 1999, 2003, 2004, 2005, 2006
Heartland Seating and Mobility Conference, Presenter	1998, 1999, 2002, 2003
Growth Conference: Sunrise Medical	January, 1996
Building Your Practice Through Managed Care	December, 1996
Spinal Management: A New Zealand Approach	December, 1995
Pediatric Study Group	1991 - 1992
Achieving Functional Outcomes in Children with Hypertonus	April, 1992
Boehme Workshop - "Handling Intensive"	September, 1991
5th Annual Traumatic Brain Injury Conference, Cedar Rapids, IA, Faculty & Presenter	October, 1990
Management of the Child with CNS Dysfunction	March, 1990

▶ References

Available upon request.

EXHIBIT B

SEATING, THE NEXT GENERATION

THOMAS R. HETZEL PT, ATP
Aspen Seating

People with disabilities are living longer. Baby boomers are coming of age and acquiring disabling conditions at an increasing rate. Ironically, improved prenatal care, neonatal care and living conditions have increased the number of children with congenital disabilities, and they are living longer. Improved trauma and ER care has increased the survival rate of people with traumatic injuries, and improved long-term management of secondary or co-morbidity factors has significantly decreased their mortality rate. Wheeled seating and mobility providers are now faced with supporting the largest-ever generation of people aging with severe disabilities. This is the challenge.

As people age with disabilities that impair mobility, their needs for wheelchair seating and mobility solutions become more complex. In the case of acquired or traumatic injuries, early intervention has emphasized support of good skin integrity. Traditional seating interventions utilize a variety of designs and materials with the emphasis on distributing pressure evenly over the surface of the cushion support and, to some extent, controlling shear forces. To do this, a material must conform to body shape and bony prominences, and respond dynamically to movement and shear. Unfortunately, the more effective a material is at distributing pressure and controlling shear, the less effective it is at supporting postural stability. Imagine trying to walk on an air or water bed and you will understand the impact these materials have on postural control.

Aging paraplegics who have had success with traditional seating technologies are developing severe over-use syndromes of the upper extremities, chronic pain and deterioration of postural alignment and control. Their skin's tolerance of pressure, no matter how well distributed, diminishes with age. In addition, deteriorating functional independence and postural issues become superimposed over severe and chronic skin problems, and people often lose their ability to sit. It is not uncommon to meet formerly active and independent paraplegics, fifteen years post-injury, relying on power or power-assisted mobility, tilt and recline systems, overhead lift systems for transfers and modified minivans for transport.

The mobility side of the industry is doing a relatively good job at introducing new and/or enhanced manual, power, and power-assisted wheelchairs with or without power seating options. The seating industry, however, has developed few significant improvements for addressing the constellation of seating challenges faced by people aging with disability. Good pressure distribution through use of foams, gels, fluids and air most often comes at the price of postural stability. The consumer and seating practitioner are forced to choose between skin OR posture. But if the provided system results in skin breakdown, it can't be used. Skin always wins.

More aggressive custom contoured systems may provide a better platform for postural control but are not appropriate for high-risk skin clients due to the systems' inability to respond to postural dynamics and positioning error. Imagine a cushion made by having the consumer sit in wet concrete. In its liquid state, the concrete will flow to conform to body shape. Once it solidifies it will match the exact shape of the consumer's bottom at that point in time. Now imagine moving even subtly within the contours of that custom seat. What happens? The relationship of bony prominences to the contours of the seat changes, and the result is increased loading of at-risk areas and unloading of areas that should be supported. Movement within the shape increases shear and thus the risk of skin break-down. This is how conventional contoured seating performs. It has little to no ability to accommodate change in a person's activities, weight, tissue atrophy, posture and functional skills.

Conventional contoured seating systems are also hot and non-breathing. Heat and moisture are gaining on pressure and shear as primary risk factors for skin breakdown, yet few wheelchair seating systems effectively reduce heat and moisture build-up at the seating interface.

In a perfect world nobody would need a wheelchair. But in this imperfect world, wouldn't it be better if people could have wheelchair seating that is built uniquely for them? That achieves optimal skin integrity

and postural control without compromise? That is breathable to keep them dry, and also help them stay warm in the winter and cool in the summer? That doesn't weigh much at all? Why not construct it in a way that ensures an accurate fit to the wheelchair to further enhance the user's balance, control and mobility? Why not make it capable of changing as a consumer's needs change?

All these goals can be achieved by presently available techniques and materials. Transfer of material technologies from other industries, coupled with orthotic and prosthetic principles, has created seating options that can be uniquely applied to each consumer. These products can promote good skin integrity without compromise of postural control. The cushion material can be breathable, thereby reducing heat and moisture build-up. Information about peoples' shapes can be captured in their wheelchairs, not in simulators detached from mobility, ensuring optimal functional performance. Though currently available on a very limited basis, this material-savvy, orthotically informed approach will define the future of seating and mobility.

EXHIBIT C

WHAT TO DO WITH THE ANTERIOR PELVIC TILT

THOMAS R. HETZEL, PT, ATP
Ride Designs

Introduction

Many people who use wheelchairs have a preference for the anterior pelvic tilt and upright to slightly forward oriented sitting, as this allows them to function. If these individuals do not receive proper training, education, and seating intervention, this persistent tendency can lead to adaptive shortening of both muscle and non-contractile tissues that limit the potential for postural correction. This workshop addresses biomechanics, evaluation, and treatment of the anterior pelvic tilt in sitting.

The Hip in Standing

The most common tendency for pelvic rotation in the seated posture is the posterior pelvic tilt. Why do people stand most commonly with an anterior pelvic tilt, yet sit with a posterior pelvic tilt? Why, with the exception of pathology typically related to the spine or hip, do people rarely stand with a posterior pelvic tilt? Why is it that some people sit with a tendency for anterior pelvic rotation?

The hip joint has greater stability in standing than it does in sitting. The hip capsule and hip flexors influence this greatly. Because hip extension is the closed pack position for the hip, standing with hip extension winds up the hip joint capsule for greater stability. One can, in fact, stand with the hip at end range of extension, relax the musculature about the hip, and not fall, as the hip capsule reaches end range and blocks further extension. The hip flexors' (iliopsoas) role further adds to the stability of the hip in standing. Originating at the iliac fossa and anterior surfaces of the lumbar vertebral bodies, and inserting on the lesser trochanter of the femur, the hip flexors' reverse muscle action is lumbar extension. Again, when standing with the hip at end range of motion of the hip flexors, the iliopsoas passively holds the pelvis anterior, and pulls the lumbar spinal segments forward to create a lumbar lordosis. The result of both actions of the hip capsule and hip flexors in hip extension is a stable hip and anterior pelvic tilt. This is why people tend to stand with anterior pelvic tilts.

The Hip in Sitting

All of the wonderful mechanics of the hip that provide stability in standing are absent in sitting. As soon as one moves into hip flexion all passive stability is lost. The hip capsule unwinds, and the hip flexors are no longer at end range. The hip, at this point, requires muscle activity to create stability. One cannot sit unsupported without muscle activity about the hip, and the most prevalent direction of pelvic rotation when attempting this is posterior. This is why people tend to sit in a posterior pelvic tilt, and why people with weakness or paralysis of the hip musculature have little choice but to sit posteriorly.

Why then do some folks sit with an anterior pelvic tilt? This is more difficult to explain, but observation of sitters for a great length of time has led this author to speculate that, in many cases, it may be secondary to disease progression. As a category, people with slow progressive neuromuscular diseases seem to have a greater propensity for an anterior pelvic tilt in sitting. It is possible that people, who have experienced normal development, and then experience the slow debilitating process of a progressive neuromuscular disease, maintain a preference for the anterior pelvic tilt, and upright to slightly forward oriented sitting. This allows them to function. As the muscles that allow the person to sit actively in this position weaken, the tendency to collapse passively into an anterior pelvic tilt and exaggerated lumbar lordosis strengthens. A common exception to this theory are children with Spina Bifida, but many of them do ambulate, often with bracing, early in life, but abandon ambulation later for more efficient wheeled mobility. Having had the experience and developmental benefits of

weight bearing through ambulation, they share the preference of anterior tilt in sitting with people who experience normal development prior to onset of disability such as muscular dystrophy and multiple sclerosis. If these individuals do not receive proper training, education, and seating intervention, this persistent tendency can lead to adaptive shortening of both muscle and non-contractile tissues which limits the potential for postural correction.

The Process of Assessment and Intervention

Although this course focuses primarily on seating intervention, it is very important that clinicians and suppliers conduct a thorough evaluation to determine all factors influencing their clients' ability to sit safely and function in their wheelchairs. Intervention is directed towards optimal postural alignment for nondestructive resting postures and preparation for and support of mobility and function. Intervention must be mindful of what people need to do in their wheelchairs, how long they must do "it", and in what environments. People must be supported in a fashion that promotes maximal independence in mobility and function, yet protects them from skin breakdown.

Intervention

In a most simplistic interpretation of a wheelchair seating assessment, virtually any finding will have an implication for intervention in at least one of the four following categories:

1. Angles. Any limitation of postural flexibility will have an impact on the angular relationships of seating supports.
2. Shape. Although many people may have the ability to sit at roughly the same angular relationships, everyone has a unique shape. Each individual's unique shape will determine the contours of the supports chosen.
3. Orientation. Once angles and shapes are determined, the orientation of the seating relative to gravity, method of mobility, and environments of use must be determined.
4. Materials. The choice of materials is tied to many factors including skin care, postural control, breathability and maintenance.

Interventions for the sitter with an anterior pelvic tendency versus the posterior pelvic tendency are very different. Location of support surfaces and orientation of supports relative to gravity are nearly opposite. Lack of attention to these differences often results in people with posterior tendencies sliding out of their chairs, and people with anterior tendencies falling forward away from their back supports. A basic understanding of these principles will lead to more effective seating intervention for the long term.

The anterior pelvic tilt and forward orientation of trunk relative to pelvis is a very functional posture. When actively controlled, this posture provides access to all kinds of functional activities. Almost everything an able-bodied person does functionally is preceded by an active anterior and lateral weight shift, so it should be of no surprise that a person with a disability desires the same. The problem experienced by a person with a disability occurs when the ability to sustain active control in an anterior orientation diminishes, but the desire to be forward does not. This leads to a passive collapse into the anterior posture, and becomes a destructive resting posture. Over time the hip flexors adaptively shorten and the hip capsule may lose flexibility. As the tendency persists, the lumbar lordosis increases, and the thoracic spinal curve may reverse from a normal kyphosis to a lordotic curve. The cervical curve may increase or decrease depending on the degree of forward rotation at the hips.

Try sitting upright maintaining your shoulders in alignment over your hips while slowly exaggerating your lumbar and thoracic extension to the extent that you can. What happens in your cervical spine as your thoraco-lumbar lordosis increases? You experience a flattening or reduction of the cervical lordosis, i.e. flexion of the cervical spine as a compensatory measure to maintain visual orientation. Now attempt to "lock" your spinal curves and rotate forward at the hip about 45 degrees. You must now extend the cervical spine and use capital extension to restore visual orientation. Continue to

rotate forward at the hips, but maintain forward gaze, until you can prop your elbows on your knees. Has your cervical and capital extension increased? Now completely relax everything except your head and neck. You are now experiencing the latent result of prolonged forward orientation with the progression of disability. You can move out of this posture, but imagine a person experiencing this progression over a period of years, rather than minutes, with limited ability to actively move out of this tendency. Simulate this long-term consequence by actively locking your entire hip, spine, and head alignment. Now "tilt" yourself posteriorly until your shoulders are once again above or slightly behind your hips, but don't let your head and neck flex. You are now looking at the ceiling and experiencing one reason why tilt as an intervention this late in the game is not possible because of contractures of the cervical and capital extensors. The person can no longer flex at the head and neck to restore visual orientation.

What can be done to reverse this scenario? Early and aggressive intervention and education is the key. Once this tendency is identified, the person and caregivers must be instructed in the potential consequence of persistent forward orientation. Taking them through the exercise above is a powerful tool. Once you have gained understanding of the scenario, you can then begin intervention.

Early Intervention

The goal of early intervention is not to block a person's ability to transition forward, but to influence how they move forward for function and to create support for a non-destructive resting posture. A posterior slope of the seat will promote a posterior tendency of the pelvis, yet observation of most seating interventions for "anterior tilters" reveals level to minimal posterior slope. A posterior slope of the seat will help keep the pelvis and lumbar spine stabilized into a back support during rest, and promote use of trunk flexion, rather than hip flexion, to transition forward for function. The choice of seating and manual wheelchair options that allow for adjustment of seat and back angle over time to maintain postural flexibility and optimal function is essential. Once the sitter loses the ability to actively restore a resting posture with good spinal alignment and pelvis and lumbar spine stabilized into a back support, progression of contractions may rapidly ensue.

If a manual wheelchair continues to be the choice for mobility, then passive stabilization of the pelvis and lumbar spine into the back support may be an option. You may try a well padded 4-point mount pelvic positioning belt capturing the ASIS with a horizontal direction of pull towards the back canes with the additional strap directed vertically to the seat-rails to prevent upward movement of the belt into the abdomen. If the tendency for collapse is too strong, this intervention may result in skin irritation or breakdown at the ASIS. In this case, an abdominal panel capturing the ASIS and abdomen may be necessary. If left untreated the anterior collapse may result in loading of the ASIS directly on to the femurs leading to skin breakdown and numerous other complications.

If power mobility is chosen, then power tilt, along with a very generous dose of education, is essential. Often times a person with the desire to be forward for function may be unaware of the need to reverse the tendency during rest, and will instead prop forward on their elbows to relax. Persistence in this habit results in the debilitating progression outlined above. Educating a sitter to use the tilt function to restore the support of his/her trunk into a back support during rest is critical. Doing this early and often is key in maintaining hip and spinal flexibility, and warding off the need for anterior trunk supports. Instruct the client to tilt forward for functional activities, and tilt back for rest. The earlier the intervention, the lesser amount of tilt will be needed to restore the trunk into a back support. Tilt will most likely be needed for regular pressure relief as well, and the person needs to be educated to tilt the system fully for an effective weight shift.

A word about the environment and out-of-wheelchair positioning

Don't assign all responsibility for long term postural care and functional sitting postures to the wheelchair. Ensure that work, home, recreational and educational environments are evaluated and modified to reduce the need for anterior trunk orientation. Assess sleeping postures, as well as all other out-of-wheelchair positions and supports. It is not uncommon to discover that these out of wheelchair positions and activities are feeding into the overall scenario of deterioration. It is also possible to restore or maintain a person's ability to sit by addressing out-of-wheelchair support and activities.

Summary

Pelvic tendencies in standing versus sitting are different. Understanding why is essential for a wheelchair seating practitioner. Assessment of people relative to their predominant pelvic tendency in sitting is a necessary step in determining appropriate seating intervention. Accurate assessment will lead to definition of clear goals and successful interventions. Effective wheelchair seating will help secure long-term optimal postural alignment for nondestructive resting postures and preparation for and support of mobility and function.

Speaker Bio

Tom Hetzel is an owner and operator of Ride Designs in Denver, Colorado. He can be reached at 866.781.1633, or tom@ridedesigns.com.

EXHIBIT D

Understanding And Caring For The Posterior And Anterior Pelvic Tilt

Thomas Hetzel
Ride Designs

Introduction
The most common tendency for pelvic rotation in the seated posture is the posterior pelvic tilt. Why do people stand most commonly with an anterior pelvic tilt, yet sit with a posterior pelvic tilt? Why, with exception of pathology typically related to the spine or hip, do people rarely stand with a posterior pelvic tilt? Why is it that some people sit with a tendency for anterior pelvic rotation? The answer lies in the difference of hip mechanics in standing versus sitting.

It is extremely important to understand the biomechanics of the hip and spine as they relate to pelvic tendencies, pelvic mobility, and pelvic stability. Even a person who sits with that perfect "neutral" pelvis has a predominant tendency towards posterior or anterior pelvic rotation.
It is well accepted that supporting a person in sitting in a fashion that promotes an upright, balanced and "neutral" pelvis is the key to good spinal alignment, which in turn facilitates optimal head and neck as well as scapular-thoracic alignment. Factors determining a person's ability to sit upright, and interventions to accomplish this lofty goal are less understood.

This presentation will attempt to explain basic causative and corrective factors associated with the anterior and posterior pelvic tendencies. General guidelines for wheelchair seating intervention will be explained relative to a sitter's tendency, cause of the tendency, flexibility, and tolerance for correction. The focus will be on biomechanics of correction and stabilization of the posterior and anterior pelvic tendencies with an emphasis on how angular relationships, shapes, and orientation of seat and back supports impact postural alignment. Certainly a person's risk for skin breakdown will impact seating intervention.

The Hip in Standing
The hip joint has greater stability in standing than it does in sitting. The hip capsule and hip flexors influence this greatly. Because hip extension is the closed pack position for the hip, standing with hip extension winds up the hip joint capsule for greater stability. One can, in fact, stand with the hip at end range of extension, relax the musculature about the hip, and not fall, as the hip capsule reaches end range and blocks further extension. The hip flexors' (iliopsoas) role further adds to the stability of the hip in standing. Originating at the iliac fossa and anterior surfaces of the lumbar vertebral bodies, and inserting on the lesser trochanter of the femur, the hip flexors' reverse muscle action is lumbar extension. Again, when standing with the hip at end range of motion of the hip flexors, the iliopsoas passively holds the pelvis anterior, and pulls the lumbar spinal segments forward to create a lumbar lordosis. The result of both actions of the hip capsule and hip flexors in hip extension is a stable hip and anterior pelvic tilt. This is why people tend to stand with anterior pelvic tilts.

The Hip in Sitting
All of the wonderful mechanics of the hip that provide stability in standing are absent in sitting. As soon as one moves into hip flexion all passive stability is lost. The hip capsule unwinds, and the hip flexors are no longer at end range. The hip, at this point, requires muscle activity to create stability.

One cannot sit unsupported without muscle activity about the hip, and the most prevalent direction of pelvic rotation when attempting this is posterior. This is why people tend to sit in a posterior pelvic tilt, and why people with weakness or paralysis of the hip musculature have little choice but to sit posterior.

Why then do some folks sit with an anterior pelvic tilt? This is more difficult to explain, but observation of sitters for a great length of time has led this author to speculate that, in many cases, it may be secondary to disease progression. As a category, people with slow progressive neuromuscular diseases seem to have a greater propensity for an anterior pelvic tilt in sitting. It is possible that people who have experienced normal development, and then experience the slow debilitating process of a progressive neuromuscular disease, maintain a preference for the anterior pelvic tilt, and upright to slightly forward oriented sitting, as this allows them to function. As the muscles that allow the person to sit actively in this position weaken, the tendency to collapse passively into an anterior pelvic tilt and exaggerated lumbar lordosis strengthens. If these individuals do not receive proper training, education, and seating intervention, this persistent tendency can lead to adaptive shortening of both muscle and non-contractile tissues that limit the potential for postural correction.

The Process of Assessment and Intervention

Although this course focuses primarily on seating intervention, it is very important that clinicians and suppliers conduct a thorough evaluation to determine all factors influencing their clients' ability to sit safely and function in their wheelchairs. Intervention is directed towards optimal postural alignment for nondestructive resting postures and preparation for and support of mobility and function. Intervention must be mindful of what people need to do in their wheelchairs, how long they must do "it", and in what environments. People must be supported in a fashion that promotes maximal independence in mobility and function, yet protects them from skin breakdown.

Intervention

In a most simplistic interpretation of a wheelchair seating assessment, virtually any finding will have an implication for intervention in at least one of the four following categories:

1. Angles. Any limitation of postural flexibility will have an impact on the angular relationships of seating supports.
2. Shape. Although many people may have the ability to sit at roughly the same angular relationships, everyone has a unique shape. Their unique shape will determine the contours of the supports chosen.
3. Orientation. Once angles and shapes are determined, the orientation of the seating relative to gravity, method of mobility, and environments of use must be determined.
4. Materials. The choice of materials is tied to many factors including skin care, postural control, breathability and maintenance.

Interventions for the sitter with an anterior pelvic tendency versus the posterior pelvic tendency are very different. Location of support surfaces and orientation of supports relative to gravity are nearly opposite. Lack of attention to these differences often results in people with posterior tendencies sliding out of their chairs, and people with anterior tendencies falling forward away from their back supports. A basic understanding of these principles will lead to more effective seating intervention for the long term.

Summary

Pelvic tendencies in standing versus sitting are different. An understanding of why this is so is essential for a wheelchair seating practitioner. Assessment of people relative to their predominant pelvic tendency in sitting is a necessary step in determining appropriate seating intervention. Accurate assessment will lead to definition of clear goals and successful interventions. Effective wheelchair seating will help secure long-term optimal postural alignment for nondestructive resting postures and preparation for and support of mobility and function.

Tom Hetzel is an owner and operator of Ride Designs in Denver, Colorado. He can be reached at 866.781.1633, or tom@ridedesigns.com.

EXHIBIT E

Orthotic Seating: A Case Study for Optimal Outcome in Spinal Cord Injury

Kendra Betz
VA Puget Sound / University of Washington / Private Practice

An appropriate seating system functions as an orthosis by providing customized support for optimized function in a wheelchair. Along with support for function, the orthotic seating system must provide skin protection while being comfortable and durable. When properly designed, fabricated and fit, the seating system as a mobility orthosis can promote maximal functional potential for clients with complex needs (1). When providing custom orthotic seating it is critical work with an appropriately skilled orthotist who can build the system AND provide the appropriate interface with the wheelchair.

Individuals with longstanding Spinal Cord Injury (SCI) present with unique and complex issues relative to seating and mobility. Impaired function as a result of paralysis, postural deformity, impaired sensation and altered skin integrity create challenges for long term successful seating interventions. To address these complex issues, the seating system designed as an orthotic device offers great benefit to individuals with SCI. Following is a case presentation to demonstrate the effectiveness of a custom seating orthosis for an SCI client.

Client Background:

DS is 40 yo African American male with C5 ASIA A tetraplegia since 1991. He underwent a left gluteal fasciocutaneous rotation flap 12/2/04 to resolve a grade 4 sacral wound. Prior to surgery, the wound was persistent for 7 months despite debridement of necrotic tissue and diligent attempts at conservative wound healing. Pertinent PMHx is significant for three prior gluteal rotation flaps in 1994, 1997 and 1999 for sacral and right ischial wounds.

Following a 21 day immobilization in a Clinitron bed s/p flap procedure, DS was mobilized to his existing seating system (see description below) with gradual increased sitting time to 4 hours without compromised skin integrity. He was discharged to home 1/21/05 with plan to continue progression of sitting time with assistance of caregivers for transfers and skin monitoring. After progression to 6 hours sitting time the following week, a wound developed at the flap scar line at mid sacrum. The new wound required readmission to the hospital with return to a Clinitron bed and application of electrical stimulation to facilitate wound healing. The wound healed in early March. He was mobilized with gradual progressed sitting time to 6 hours prior to discharge to home on March 11. One week later, the midline flap line was compromised again with a grade 2 wound measuring 6.3 cm long and 1.5 cm wide. At that time, he was referred for evaluation for a custom seating orthosis.

Client Evaluation

<u>Subjective</u>: Pt's primary complaints are 1) frustration with continued compromised wound at flap line 2) shift (decline) in seated position throughout the day and 3) impaired daily life due to longstanding limited sitting time. His goals are a) wound to heal and remain closed b) symmetric sitting posture for improved appearance and c) all day sitting.

<u>Initial seating system</u>: Invacare Storm with power tilt seat. Sits on high profile Roho with Jay ½" soft lift under R posterior aspect of cushion to function as obliquity lift. Solid curved backrest with R lateral support positioned 2" below axilla. Headrest at midline. Drives independently with RUE with goalpost joystick. Operates power tilt system independently.

<u>Postural presentation</u>: sits with R pelvic obliquity with shoulders level. Space between iliac crest and ribs is 2.5 fingers R, 1 left. Pelvis is anterior with exaggerated lumbar lordosis. Right pelvis, trunk and shoulder rotated forward. Trunk is shifted to R with heavy contact at lateral support. Head is shifted to R of headrest. Legs in "windswept" position to the left (left leg in abduction and ER with right leg in adduction and IR) with correlated foot position. (Figure 1)

<u>Mat evaluation</u>: a thorough mat evaluation was complete with the following findings . . .

LE PROM in degrees

	LEFT	RIGHT	NORMAL
Hip extension	-45	-40	+15
flexion with knee flexed	110	95	120
flexion with knee extended (SLR)	40	40	70
adduction	30	20	30
abduction	10	20	45
internal rotation	10	25	45
external rotation	30	15	45
Knee extension	-15	0	0
flexion	115	125	135
Ankle dorsiflexion	0	5	20

Range of motion limitations directly correlated with postural asymmetry. Trunk and pelvis positions partially flexible in three planes. Unable to achieve neutral frontal plane pelvic alignment or trunk symmetry. Lumbar hyperextension reduced with bilateral hips flexed to 45 degrees. Rotation forward of right pelvis neutralized when ROM limits at hip flexion respected. Mild extensor tone in trunk and LE's (takes baclofen 120 mg/day and diazepam 20 mg/day). Skin inspection reveals sacral Grade 2 wound (6.3 x 1.5 cm) at midline flap.

Intervention:

Evaluation findings indicate that DS best served with a seating orthosis that provides custom contouring for both sitting surface and trunk given presentation of asymmetric trunk alignment with limited flexibility. If trunk had available frontal plane flexibility to allow neutral alignment, a custom contoured cushion with off-shelf contoured backrest may have sufficed.

The client's shape was captured for fabrication of custom Aspen Seating Orthosis (ASO). The shape of his sitting surface was captured in existing EWC with Ride simulator as per Ride Technical manual (2). Pelvis and leg alignment was optimized with the foam capture based on findings from the mat evaluation. The shape of his trunk was captured via indirect vacuum consolidation with a molding bag. A similar process is described in Cook & Hussey (3). During the molding process, lumbar hyperextension was reduced and rotations neutralized. The shapes were shipped to the manufacturer/orthotics lab in Denver for fabrication.

The final product (ASO) consists of a vacuum formed polypropylene shell with a contoured backrest and Ride custom cushion insert specifically designed to interface into the shell. The system utilizes Brock ™ composite, a closed cell breathable foam that provides moisture and temperature management. The ASO was installed on the existing power chair solid seat with the original backrest removed. The contours of the ASO seat and backrest allow for correction of postural alignment within available flexibility while accommodating physical limitations. By design, the ischials, sacrum, coccyx and bilateral trochanters are off-loaded via the concept of force isolation where pressures are shifted away from high risk bony prominences to areas that are more tolerant (4). The firm contoured cushion and interfaced trunk support provides proximal stability at the pelvis and trunk. This allows optimized function of the upper extremities, relaxation into a supported position, and comfort for prolonged sitting.

Outcome:

The client's postural support is optimized in the ASO. The partially flexible R pelvic obliquity is improved with space IC to ribs now 2 fingers R, 1.5 left. Pelvis is neutral in the sagital plane with lumbar spine in full contact with customized midline contours at anterior aspect of the backrest. The pelvis and trunk are neutral in the transverse plane (rotation). Head is balanced and aligned with center mount headrest. Bilateral legs rest in neutral position with elimination of windswept deformity. Feet are neutral on footplates (Figure 2).

Skin issues are resolved in the custom system. Pressure mapping reveals complete offload at the ischii, sacrum/coccyx and bilateral trochanters. After just 2 weeks of gradually increased sitting time in ASO, the sacral wound was completely closed without evidence of compromised skin integrity at the sitting surface or trunk (5). The patient reports sitting 12 hours/day without discomfort or shift in position. Eleven months after issue of ASO, skin remains intact and client is sitting all day with consistent comfort and support.

Patient Education:

In conjunction with issue of ASO, DS and his caregivers were trained in safe transfers to/from the device and appropriate positioning within the seating orthosis. Continued power tilt pressure releases and consistent skin inspection was encouraged. Attention to skin issues on other surfaces (i.e. bed, bathroom equipment) was emphasized. A concentrated stretching program was prescribed to target limited cervical, trunk and LE contractures. Additionally, concepts for positioning in bed to combat effects of gravity on paralyzed body during all-day sitting were also discussed. The ASO will be re-assessed by an orthotist/therapist team on an annual basis with adjustments completed as indicated.

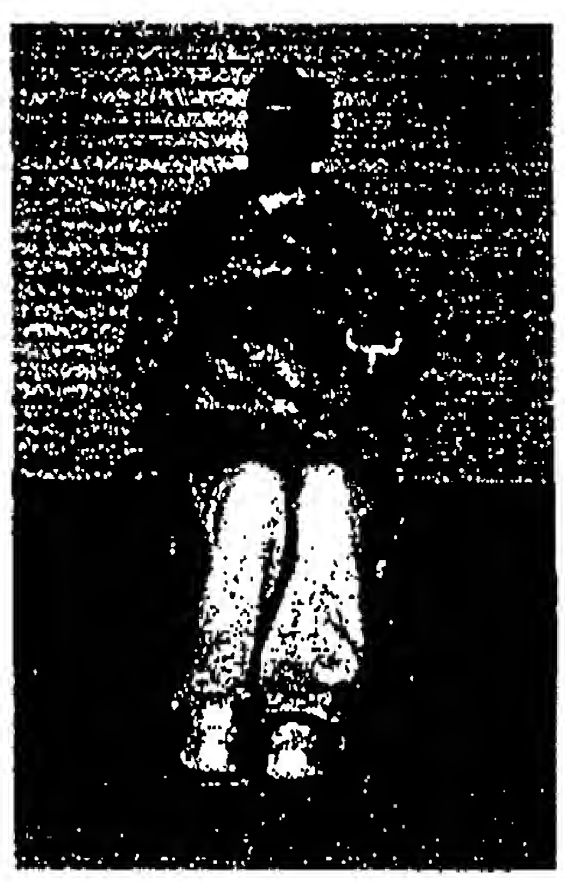

Figure 1: Original System

Figure 2: Aspen Seating Orthosis

DISCUSSION & CONCLUSIONS

There are several key features of the ASO that contribute to its efficacy. A seating system that is custom contoured to an individual's shape provides the greatest amount of support (2), thereby allowing the individual to have proximal stability for distal mobility. The final shape and extent of the ASO contours are based on a thorough client exam which is consistent with the recommendation that postural supports for the SCI client should match the available ROM and sitting balance (6). The stability of the pelvis is addressed via the custom contoured firm sitting surface as well as the interface with the contoured backrest. The cushion/back interface in the ASO likely works because

there is appropriate support for the posterior pelvis, there is adequate lateral support for the pelvis and lumbar spine, extension in the thoracic spine is encouraged while controlled and the head and neck are balanced (7). Because the client's shape was captured in optimum orientation relative to gravity, the final system allows him to sit relaxed with gravity assisting trunk elongation and balanced head position. Contoured cushions have been shown to provide improved pressure distribution compared to cushions without anatomical contour (8). The approach for skin protection via force isolation is indicated in this case where a pressure distribution model was not effective in keeping skin intact. Additionally, shear is reduced at the seat when adequately interfaced with a contoured backrest which greatly contributes to skin health (7). The potential concerns with custom contoured seating systems, such as difficulty with transfers and correct positioning, were addressed with client education and attendant training. Unlike many custom contoured seating technologies, the ASO can be modified to meet the client's changing needs.

This case clearly demonstrates a successful outcome for providing a custom seating orthosis for an individual with SCI. Conventional, off shelf seating products were not adequate in providing the necessary support and skin protection to allow this individual to sit and function as a full time wheelchair user. The ASO allows him to sit full time with support, comfort and intact skin. Although this case may appear excessively complex given the extensive history of skin compromise combined with postural deformity and range of motion limitations, this presentation is not uncommon for individuals with long-standing SCI. The ASO is more expensive than conventional seating products which is consistent among custom equipment and is expected due to manufacturing costs and direct customer service needs. However, the relative cost of a custom seating orthosis is minimal compared to the astronomical costs of treating pressure ulcers, which are the most frequent secondary medical complication in SCI (7) and a leading cause for rehospitalization after traumatic SCI (8). Improved quality of life for the SCI client is perhaps the most valuable outcome of a successful seating intervention.

The ASO is an appropriate consideration for individuals with SCI who will benefit from a custom contoured device that provides postural support, skin protection, comfort and stability for optimized function.

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EXHIBIT F

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

MEDI :ARE

Part A Inte mediary
Part ; Carrier
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January 30, 2006

Thomas R. Hetzel, PT, ATP
CEO
Ride Designs, a branch of Aspen Seating, LLC
4251-E S. Natches CT
Sheridan, CO 80110

Re: Ride R1 (Models R1-1414, R1-1416, R1-1516, R1-1518, R1-1616, R1-1617, R1-1618, R1-1 520, R1-1716, R1-1717, R1-1718, R1-1816, R1-1818, R1-1820, R1-2020, R1-2220, R1-2222, R1-24 :0, R1-2422)

Dear Mr. Hetzel:

This letter is in response to your recent inquiry for coding verification of the above listed product(s) manufactured by your company. The Statistical Analysis Durable Medical Equipment Regional Can .er (SADMERC) has reviewed the documentation and information submitted for HCPCS Coding. The SADMERC conducts reviews of products to determine the correct HCPCS code(s) of DMEPOS prc luct(s) for Medicare billing.

It is our determination that the Medicare HCPCS code(s) to bill the four Durable Medical E juipment Regional Carriers (DMERCs) is/are:

E2607 Skin protection and positioning wheelchair seat cushion, width less than 22 inches, any depth.

E2608 Skin protection and positioning wheelchair seat cushion, width 22 inches or greater, an / depth.

This HCPCS coding decision applies to the submitted product(s) as presented to and review d by the SADMERC. Any modifications to the product(s) could change the HCPCS code and would n :ed to be reviewed for coding verification. The assignment of a HCPCS code to the product(s) should in r o way be construed as an approval or endorsement of the product(s) by SADMERC or Medicare, nor does i imply or guarantee claim reimbursement or coverage. For questions regarding claim coverage or reiml ursement please contact your regional DMERC.

Should you disagree with this coding decision, a re-review of the product(s) can be initial ed. The SADMERC will provide a re-review if the request is made within 45 days of the date of this etter and additional documentation is provided supporting the request. If a request for a re-review is mad ; after 45 days, the request is treated as a new Coding Verification Review and a complete applicatior must be submitted along with the additional documentation supporting the request.

Should you have any questions regarding this decision, please contact me at the address bel w or by telephone at (803) 763-8707.

Sincerely,

Bobbie Taylor

Bobbie Taylor, RN
HCPCS Medical Analyst
SADMERC